



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

m426m

**WARNING LETTER**

August 30, 2000

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

REF: NYK-2000-95

Anna Kanopa  
Radiology Administrator  
St. James Mercy Hospital  
411 Canisteo Street  
Hornell, NY 14843

Facility ID: 138685

Dear Ms. Kanopa:

Your facility was inspected on August 28, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration. This inspection revealed serious regulatory problems involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

*(1) Phantom QC records for the [REDACTED] Medical Systems unit #2 were missing for 6 weeks between 8/13/99 and 10/1/99.*

The specific problem noted above appeared on your MQSA Facility Inspection Reports which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

St. James Mercy Hospital  
Warning Letter NYK-2000-95

There were also Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings were:

- (1) There is no written procedure for handling consumer complaints.*
- (2) There is no written procedure for infection control.*
- (3) Corrective action for a failing image score (before further exams) was not documented for the [REDACTED] Medical Systems unit #2. Out of control limits were noted for phantom density difference on 8/6/99, 1/7/00 and 1/13/00.*

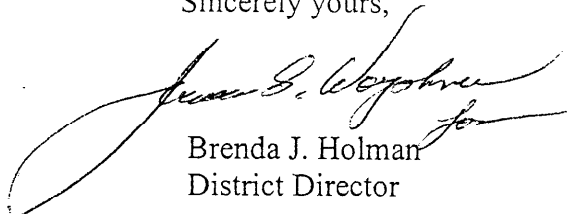
It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Brenda J. Holman  
District Director

St. James Mercy Hospital  
Warning Letter NYK-2000-95

cc: Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 22091

cc: Gerald O'Connor  
New York State Dept. of Health  
Flanigan Square, Room 530  
547 River Street  
Troy, NY 12180

cc: Robert P. Snyder  
New York State Dept. of Health (BERP)  
42 South Washington Street  
Rochester, NY 14608-2099